

REMARKS

In response to the Office Action of April 24, 2008, Applicants have amended the claims, which when considered with the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration and allowance of all pending claims is respectfully requested. The amendments to the claims have been made in the interest of expediting prosecution of this case. Applicants reserve the right to prosecute the same or similar subject matter in this or another application.

Claims 1, 3-7, 9, 22-24 and 29-54 are pending. By this Amendment, Claims 1, 3 and 4 have been amended to further define an embodiment of the invention, i.e., to recite that component (a) is admixed with components (i), (ii) and (iii) of component (b). Support for this amendment can be found throughout the specification, e.g., paragraphs [0082] through [0084] and in the working examples. Also, by this Amendment, Claims 8, 10-21 and 25-28 have been cancelled without prejudice. Applicants reserve the right to file one or more divisional applications to the cancelled subject matter. Applicants respectfully submit that no new matter has been added to the subject invention nor have any new issues been raised by these amendments, e.g., the amendments to Claims 1, 3 and 4 would not necessitate a new search as the search carried out for original Claims 1, 3 and 4 would have already covered any search for amended Claims 1, 3 and 4 since the scope of original Claims 1, 3 and 4 covered the subject matter of amended Claims 1, 3 and 4. Accordingly, entry and consideration of the present Amendment is deemed appropriate as it places the application in condition for allowance.

The Examiner has rejected Claims 1, 5, 29-34, 37 and 42-54 under 35 U.S.C. §102(e) as being anticipated by Li et al. U.S. Patent No. 6,893,660 ("Li et al.").

Li et al. disclose stable oral controlled release solid dosage formulations without the need for acid stabilizers. Li et al. further disclose that stabilization of the controlled release solid dosage forms is achieved by sealing low and high molecular weight polyethylene oxides with a water-soluble polymer, thereby physically separating them away from the pharmaceutically active ingredient, e.g., bupropion. Thus, according to Li et al., low and high molecular weight polyethylene oxides are first sealed with a water-soluble polymer such as hydroxypropyl methylcellulose and then the sealed low and high molecular weight polyethylene oxides are combined with a composition containing the pharmaceutically active component to form a stable composition.

In contrast thereto, the solid oral controlled release pharmaceutical composition comprising (a) a therapeutically effective amount of a pharmaceutically active agent; and (b) a controlled release modifying complex of amended Claim 1 recites, *inter alia*, "wherein component (a) is admixed with components (i), (ii) and (iii) of component (b)". Therefore, the solid oral controlled release pharmaceutical composition of the present invention, as set forth in the amended claims, does not separate the pharmaceutically active agent from the controlled release modifying complex. As such, the claimed solid oral controlled release pharmaceutical composition is completely different than the stable oral controlled release solid dosage formulation of Li et al.

For the foregoing reasons, amended Claims 1, 5, 29-34, 37 and 42-54 are believed to possess novel subject matter over Li et al. Therefore withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

The Examiner has rejected Claims 1, 3-7, 9, 22-24 and 29-54 under 35 U.S.C. §103(a) as being unpatentable over Li et al. in view of Besemer et al. U.S. Patent No. 5,585,114 ("Besemer et al.") and Wadhwa U.S. Patent No. 6,642,276 ("Wadhwa").

The foregoing deficiencies of Li et al. discussed above with respect to the rejection of Claim 1 apply with equal force to this rejection. Besemer et al. and Wadhwa do not cure and are not cited as curing the deficiencies of Li et al. Rather, Applicants respectfully submit that the combination of Li et al., Besemer et al. and Wadhwa would not provide the claimed compositions in the current application. Initially, Applicants note that the main teaching of Li et al. is a pharmaceutical composition that provides additional stability without the use of stabilizers. As stated above, Li et al. were able to accomplish this by preventing direct contact between bupropion and the excipients (i.e., low and high molecular weight polyethylene oxides) with a seal coating of hydroxypropyl methylcellulose. Accordingly, the primary goal of Li et al. is to segregate the excipients from the pharmaceutically active ingredient. Therefore, the combination of the disclosures of Besemer et al. and Wadhwa with Li et al. would still result in a pharmaceutical composition in which the release modifying excipients are sealed away from the pharmaceutically active ingredient.

In contrast thereto, the solid oral controlled release pharmaceutical compositions comprising (a) a therapeutically effective amount of a pharmaceutically active ingredient; and (b) a controlled release modifying complex of amended Claims 1, 3 and 4 recite, *inter alia*, "wherein

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component (a) is admixed with components (i), (ii) and (iii) of component (b)". Therefore, Applicants invention teaches that the mixture of the pharmaceutically active ingredient and the controlled release modifying complex results in a pharmaceutical composition that synergistically extends the release of the pharmaceutically active ingredient. This is clearly *not* what would result from the combination of Li et al., Besemer et al. and Wadhwa. Thus, even by combining the disclosure of Li et al. with the disclosures of Besemer et al. and Wadhwa, one skilled in the art would not even arrive at the claimed pharmaceutical compositions.

Accordingly, amended Claims 1, 3-7, 9, 22-24 and 29-54 are believed to be nonobvious, and therefore patentable, over the combination of Li et al. with Besemer et al. and Wadhwa. Therefore withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

For the foregoing reasons, amended Claims 1, 3-7, 9, 22-24 and 29-54 as presented herein are believed to be in condition for allowance. Such early and favorable action is earnestly solicited.

Respectfully submitted,



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